IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BAYER SCHERING PHARMA AG & BAYER HEALTHCARE PHARMACEUTICALS INC. **Plaintiffs and Counterclaim Defendants,** **v.** **BARR LABORATORIES, INC.** **Defendant and Counterclaim Plaintiff.**	**Civil Action No. 05-2308 (PGS) (ES)** **Hon. Peter G. Sheridan, U.S.D.J.** **Hon. Esther Salas, U.S.M.J.** **Filed Electronically**

[JOINT PROPOSED] FINAL PRETRIAL ORDER

This matter having come before the Court for a pretrial conference pursuant to Fed. R. Civ. P. 16, Bartlit Beck Herman Palenchar & Scott, LLP; Fitzpatrick Cella Harper & Scinto; and McCarter & English, LLP having appeared for Plaintiffs Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc. (together, "Bayer Schering") and Winston & Strawn and Greenbaum Rowe Smith & Davis LLP having appeared for Defendant Barr Laboratories, Inc. ("Barr"), the following Final Pretrial Order is hereby entered:

1. **JURISDICTION:** (Set forth specifically.)

This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a).

2. **PENDING/CONTEMPLATED MOTIONS:** (Set forth all pending or contemplated motions, whether dispositive or addressed to discovery or the calendar. If the court indicated that it would rule on any matter at pretrial, summarize that matter and each party's position.)

A. Pending Motions

1) Bayer Schering's Motion *in Limine* to Exclude Certain Testimony of Barr's Expert, Dr. Walter Chambliss.

2) Barr Laboratories, Inc.'s Motion *in Limine* to Exclude Any Internal Documents Relied Upon by Schering AG, et al. to Show Evidence of Non-Obviousness.

3) Barr Laboratories, Inc.'s Motion *in Limine* to Exclude Any Documents Related to Barr's ANDA to Show Proof of Copying.

4) Barr Laboratories, Inc.'s Motion *in Limine* to Exclude Use of FDA Guidelines as Proof of the PTO's Requirements for Patentability.

5) Barr Laboratories, Inc.'s Motion *in Limine* to Exclude Any Schering AG, et al. Documents that Mischaracterize or Discuss the FDA's Opinion Regarding the Effectiveness of Drospirenone.

6) Barr Laboratories, Inc.'s Motion *in Limine* to Exclude Evidence and Arguments Concerning European Patent Proceeding.

7) Barr Laboratories, Inc.'s Motion *in Limine* to Exclude ¶¶ 67-68, 74-78, and 80-87 of the Expert Report of Thomas Foster and All Testimony Related Thereto.

8) Barr Laboratories, Inc.'s Motion *in Limine* to Exclude the Expert Report and Testimony of Janet Arrowsmith Lowe, M.D.

9) Barr Laboratories, Inc.'s Motion *in Limine* to Exclude Portions of the Expert Report of Larry S. Nixon and Testimony Related Thereto.

B. Bayer Schering's Contemplated Motions

1) Bayer Schering's Motion for Judgment on Partial Findings. *See* Fed. R. Civ. P. 52(c).

2) Bayer Schering's Renewed Motion for Judgment on Partial Findings. *See* Fed. R. Civ. P. 52(c).

C. Barr's Contemplated Motions

(none).

3. STIPULATION OF FACTS: (Set forth in narrative form a comprehensive listing of all uncontested facts, including all answers to interrogatories and admissions, to which there is agreement among the parties.)

A. Plaintiff Bayer Schering Pharma AG is a corporation organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Müllerstrasse 178, 13353 Berlin, Federal Republic of Germany.

B. Plaintiff Bayer HealthCare Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 340 Changebridge Road, Montville, New Jersey 07045-1000.

C. Defendant Barr Laboratories, Inc. ("Barr") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677.

D. U.S. Patent No. 6,787,531 ("the '531 patent"), entitled "Pharmaceutical Composition for Use as a Contraceptive," issued on September 7, 2004. Bayer Schering Pharma AG owns the '531 patent.

E. The application for the '531 patent was filed on August 31, 2000, which claims priority from provisional application No. 60/240,953, filed on August 31, 1999.

F. On March 18, 2005, Barr Laboratories, Inc. sent notice to the corporate predecessors of Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc., (together, "Bayer Schering") that the Food and Drug Administration (FDA) received Barr's Abbreviated New Drug Application (ANDA) containing bioavailability and/or bioequivalence

data from studies conducted by Barr on the 3.0 mg drospirenone and the 0.03 mg ethinyl estradiol tablets that are the subject of Plaintiff's New Drug Application (NDA) No. 21-098. Barr's ANDA was assigned No. 77-527 by the FDA.

G. Barr filed a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") asserting that the '531 patent was invalid and not infringed.

H. Barr stipulates that its ANDA product No. 77-527 (the "ANDA product") would infringe claims 1, 5, 8, 27, 28, 29, 30, 33, 36, 49 and 50 (the "asserted claims") of the '531 patent.

4. **PLAINTIFFS' CONTESTED FACTS**: (Stated separately for each defendant. Proof shall be limited at trial to the matters set forth below. Failure to set forth any matter shall be deemed a waiver thereof.)

A. Plaintiffs intend to prove the following contested facts with regard to liability:

1) As the '531 patent is presumed valid, Bayer Schering has **no burden of proof** regarding Barr's allegation that the asserted claims of the '531 patent are invalid or unenforceable. Barr alone must prove its case by clear and convincing evidence. Without assuming any burden of proof, Bayer Schering expects Barr to contest the following facts at trial:

2) It would not have been obvious to a person of ordinary skill in the art at the time the invention was made to formulate an oral contraceptive with low dose, micronized drospirenone and expose it to the gastric environment (stomach acid) upon dissolution.

3) Bloating, a common side effect of oral contraceptive use, has a significant effect on proper usage and compliance with an oral contraceptive regimen.

4) A formulator of ordinary skill, when developing an oral contraceptive, would seek to preserve drospirenone's anti-bloating effect.

5) The prior art, alone or in combination, does not teach any one of the asserted claims of the '531 patent.

6) The subject matter as a whole of each of the asserted claims of the '531 patent would not have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

7) The prior art (including but not limited to Nickisch 1986) teaches away from the asserted claims of the '531 patent.

8) There are objective indicia of the non-obviousness of the asserted claims, including but not limited to commercial success, copying of others, skepticism of experts, and unexpected results.

9) The U.S. clinical trial of Yasmin® was not public.

10) The U.S. clinical trial of Yasmin® was conducted for an experimental purpose.

11) The invention described in the '531 patent was not reduced to practice until the completion of the U.S. clinical trial of Yasmin®.

12) There were no material misstatements in the Declaration of Herman Ellman ("Ellman Declaration") submitted to the U.S. Patent & Trademark Office ("PTO") during prosecution of the '531 patent.

13) Dr. Herman Ellman had no intent to deceive the PTO when he filed his declaration in support of the '531 patent application.

14) There were no material misstatements in the Declaration of Ralph Lipp ("Lipp Declaration") submitted to the PTO during prosecution of the '531 patent.

15) Dr. Ralph Lipp had no intent to deceive the PTO when he filed his declaration in support of the '531 patent application.

16) Finally, Bayer Schering contests all factual statements contained in Barr's statement of contested facts, Section 5, *infra*. Bayer Schering further contests each of the legal conclusions that Barr mischaracterizes as contested "facts."

B. Plaintiffs intend to prove the following contested facts with regard to damages: (This must include each item of damages, the amount of each item, the factual basis for each item and, if punitive damages are claimed, the facts upon which plaintiff will rely to establish punitive damages.)

1) At present, Bayer Schering does not seek damages in this action and does not intend to prove any facts relating to damages.

2) By virtue of Barr's stipulated infringement of the asserted claims of the '531 patent, Bayer Schering is entitled to a permanent injunction against Barr and its officers, agents, attorneys, and employees and those acting in privity or concert with it, enjoining them from engaging in the commercial manufacture, use, offer to sell, or sale within United States, or importation into the United States, of Barr's ANDA product described in its ANDA No. 77-527.

3) By virtue of Barr's stipulated infringement of the asserted claims of the '531 patent, Bayer Schering is entitled to an order that the effective date of any approval of Barr's ANDA No. 77-527 be a date which is not earlier than the expiration date of the '531 patent or any later date of exclusivity to which Bayer Schering becomes entitled.

5. DEFENDANT'S CONTESTED FACTS: (Stated separately for each plaintiff. See instructions above.)

A. Defendant intends to prove the following contested facts with regard to liability:

1) As part of its ANDA, Barr filed a Paragraph IV certification asserting that U.S. Patent No. 6,787,531 ("the '531 patent") was invalid, unenforceable or otherwise not infringed by Barr's proposed ANDA product..

2) Barr is the first ANDA applicant to file a Paragraph IV certification to Plaintiffs' NDA 21-098, and thus is eligible for 180-days of marketing exclusivity if it prevails in the present cause of action.

3) The '531 patent claims priority to provisional application No. 60/240,953 ("the '953 provisional application"), filed on August 31, 1999. The critical date for purposes of patentability under 35 U.S.C. § 102(b) is August 31, 1998.

4) The '531 patent is invalid because it would have been obvious to one of ordinary skill in the art under 35 U.S.C. § 103.

5) It would have been obvious to one of ordinary skill in the art at the time the '953 provisional application was filed to micronize 3.0 mg of drospirenone for use in an oral dosage form exposed to the gastric environment upon dissolution.

6) The prior art as of August 31, 1999—including the 1986 Nickisch Reference—would not teach a person of ordinary skill in the art away from formulating an oral contraceptive dosage form that includes 3.0 mg of micronized drospirenone exposed to the gastric environment upon dissolution.

7) The '531 patent is invalid under 35 U.S.C. 102(b) because the invention described in the asserted claims was publicly used in the U.S. prior to August 31, 1998.

8) During the years 1990-1996, Plaintiffs conducted numerous Phase I, II and III clinical trials in Europe in which the invention described in the asserted claims of the '531 patent was administered to more than 2,000 human females.

9) After the European Phase II clinical trials, Plaintiffs determined that the invention described in the asserted claims of the '531 patent was safe and effective for use in human females.

10) Several times during the European Phase III clinical trial, and at the end of the trial, Plaintiffs acknowledged that the invention described in the asserted claims of the '531 patent was safe and effective for use as an oral contraceptive in human females.

11) Before commencing the U.S. Phase III clinical trial in December 1996, the invention described in the asserted claims of the '531 patent had already been reduced to practice.

12) The U.S. Phase III clinical trial was not experimental in nature.

13) The human female patients involved in the U.S. Phase III clinical trial knew that they were receiving Yasmin®, which is the commercial embodiment of the invention described in the asserted claims of the '531 patent.

14) The human females that participated in the U.S. Phase III clinical trial were provided several months worth of Yasmin® to take home and self-administer on a daily basis.

15) The human females that participated in the U.S. clinical trial were under no confidentiality obligations.

16) The human females that participated in the U.S. clinical trial were not under the control of the Plaintiffs or inventors of the '531 patent.

17) The '531 patent is not enforceable due to inequitable conduct before the United States Patent and Trademark Office ("USPTO").

18) During prosecution of the '531 patent, Plaintiffs submitted a declaration from Dr. Herman Ellman to the USPTO to overcome a patentability rejection.

19) Dr. Herman Ellman, an employee of Plaintiffs during the 1990's, was aware that the safety and efficacy of the invention described in the asserted claims of the '531

patent had already been determined as a result of Plaintiffs' European Phase II and III clinical trials.

20) Notwithstanding, Dr. Ellman's declaration states that (1) the safety and efficacy of the claimed formulation had not yet been determined at the time of the U.S. clinical trials, and (2) the U.S. clinical trials were purely experimental.

21) Accordingly, Plaintiffs, Dr. Ellman and others substantively involved in the prosecution of the '531 patent submitted materially false information to the patent examiner with the intent to deceive him into believing that the claims of the '531 patent were patentable.

22) Dr. Ellman's declaration failed to disclose to the patent examiner the results of Plaintiffs' European Phase II and III clinical trials, which established safety and efficacy in human females.

23) Accordingly, Plaintiffs, Dr. Ellman and others substantively involved in the prosecution of the '531 patent, failed to disclose material information to the patent examiner with the intent to deceive him into believing that the claims of the '531 patent were patentable.

24) During prosecution of the '531 patent, Plaintiffs submitted a declaration from Dr. Ralph Lipp to overcome a patentability rejection.

25) Dr. Lipp's declaration references Appendix B, which is a summary prepared by him of various prior art references that he cites in support of his testimony that micronization does not always lead to an increase in bioavailability.

26) Appendix B of Dr. Lipp's declaration mischaracterizes and inaccurately states the source of his quotes.

27) Appendix B of Dr. Lipp's declaration provides quotes that do not appear in the cited references.

28) None of the articles that Dr. Lipp cites in his declaration support his testimony that micronization of poorly water soluble drugs does not always lead to an increase in bioavailability.

29) Accordingly, Plaintiffs, Dr. Lipp and others substantively involved in the prosecution of the '531 patent, submitted materially false information to the patent examiner with the intent to deceive him into believing that the claims of the '531 patent were patentable.

30) Finally, Barr contests all the factual statements contained in Plaintiffs' statement of contested facts, Section 4, infra. Barr further contests each of the legal conclusions that Bayer Schering mischaracterizes as "facts."

B. Defendant intends to prove the following contested facts with regard to damages: (This statement must include the factual basis for each defense against the plaintiff's claims for damages.)

1) Plaintiffs are not seeking any damages in this action. Therefore, Barr has no burden of proof at trial on the issue of damages for patent infringement.

2) Plaintiffs are not entitled to a permanent injunction against Barr and its officers, agents, attorneys, and employees and/or those acting in privity or concert with it, enjoining them from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Barr's ANDA product that is described in ANDA No. 77-527.

6. PLAINTIFFS' WITNESSES: (Aside from those called for impeachment purposes, only the witnesses whose names and addresses are listed below will be permitted to testify at trial.)

A. On liability Plaintiffs intend to call the following witnesses who will testify in accordance with the following summaries:

Bayer Schering's Will Call List

Witness	Summary
McGinity, James University of Texas College of Pharmacy University Station A1900 Austin, Texas 78712	Formulation of drospirenone and related compounds; use of enteric coatings.
Shulman, Lee 250 E. Superior St., Rm. 05-2168 Department of Obstetrics and Gynecology Feinberg School of Medicine Northwestern University Chicago, Illinois 60611	Clinical use and testing of oral contraceptives; drospirenone and its effects; importance of drospirenone's anti-bloating effect; contraceptive effectiveness; interpretation of European clinical trials with regard to contraceptive effectiveness in the United States.
Tack, Johannes Axxonis Pharma AG Schoeneberger Strasse, No. 15 Berlin, Germany	Development and testing of the claimed invention.

Plaintiffs' May Call List

Witness	Summary
Arrowsmith-Lowe, Janet Arrowsmith-Lowe Consulting, Inc. 185 Eagle Creek Canyon Ruidoso, New Mexico 88345	FDA regulatory requirements for pharmaceuticals.
Blode, Harmut Bayer Schering Pharma AG Müllerstraβe 178 13342 Berlin, Germany	Pharmacokinetics of drospirenone and other compounds.
Ellman, Herman Warner Chilcott 100 Enterprise Drive Rockaway, New Jersey 07866	U.S. clinical testing of the study drug that the FDA ultimately approved as Yasmin®.
Foster, Thomas University of Kentucky 231F College of Pharmacy 725 Rose Street Lexington, Kentucky 40536	Pharmacokinetics of drospirenone and other compounds.
Frick, Jeffrey Hill & Knowlton 909 Third Avenue New York, New York 10022	Commercial development and marketing of Yasmin®.

Witness	Summary
Funke, Adrian Bayer Schering Pharma AG Müllerstraβe 178 13442 Berlin, Germany	Development and testing of the claimed invention.
Heil, Wolfgang Am Wasserturm 24 21435 Stelle, Germany	Development and testing of the claimed invention.
Heithecker, Renate Bayer Schering Pharma AG Müllerstraβe 178 13442 Berlin, Germany	Development and clinical testing of the claimed invention and of the formulation that the FDA ultimately approved as Yasmin®.
Hümpel, Michael Singenor Weg 24 1463 Berlin, Germany	Development and testing of the claimed invention.
Lipp, Ralph 11780 Auburn Creek Crossing Zionsville, Indiana 46077	Development and testing of the claimed invention.
Nixon, Larry Nixon & Vanderhye, PC 901 North Glebe Road Arlington, Virginia 22203	Barr's allegations of inequitable conduct.
Velez, Nancy Bayer HealthCare Pharmaceuticals Inc. 340 Changebridge Road Pine Brook, New Jersey 07045	FDA regulatory approval of Yasmin®.

B. On damages Plaintiffs intend to call the following witnesses who will testify in accordance with the following summaries:

Bayer Schering does not intend to call any witnesses on the issue of damages.

C. Defendant objects to the following witnesses for the reasons stated:

Witness	Summary
Nixon, Larry	Rule 702, 401, 402, 403 – Mr. Nixon's testimony is the subject of a Barr motion-in-limine. Barr alleges that Mr. Nixon attempts to give expert opinions outside the scope of his expertise.
Arrowsmith-Lowe, Janet	Rule 702, 401, 402, 403 – Ms. Arrowsmith-Lowe's testimony regarding FDA approval is irrelevant; Ms. Arrowsmith-Lowe's testimony is the subject of a Barr motion-in-limine.
Velez, Nancy	Rule 401, 402, 403 - The FDA regulatory approval is irrelevant to current proceedings;

Witness	Summary
	Barr has filed a motion-in-limine seeking the preclusion of any testimony of FDA regulations
Foster, Thomas	Rule 702, 401, 402, 403 – Mr. Foster's testimony regarding HPLC detection limits irrelevant because it is based on unreliable science. Mr. Foster's testimony is the subject of a Barr motion in limine.

7. **DEFENDANT'S WITNESSES:** (See instructions above.)

A. On liability Defendant intends to call the following witnesses who will testify in accordance with the following summaries:

Barr's Will Call List

Witness	Summary
Bhavnani, Bhagu St. Michael's Hospital Department of Obstetrics and Gynecology Room 7-074 Bond Wing Toronto, Ontario M5B1W8	Obviousness of the claimed invention; structural and chemical similarities between spirorenone and drospirenone; whether the 1986 Nickisch Reference teaches away from the claimed invention; progestational activity of drospirenone's isomer
Boghigian, Harry 7 Tudor Place Randolph, NJ 07869	Alleged commercial success of the claimed invention
Chambliss, Walter The University of Mississippi 1006 Thad Cochran P.O. Box. 1848 University, Mississippi 38677-1848	Obviousness of claimed invention; public use of claimed invention prior to critical date; inequitable conduct during prosecution of the '531 patent
Mossinghoff, Gerry 1530 Key Boulevard Penthouse 28 Arlington, VA 22209	Prosecution history of the '531 patent; inequitable conduct during prosecution of the '531 patent, public use of the claimed invention prior to the critical date, and obviousness of the claimed invention
Nick Tantillo Barr Laboratories, Inc 400 Chestnut Ridge Road Woodcliff Lake, NJ 07677	Barr's decision to file ANDA No. 77-527
Pramar, Yashoda 209 Crystal Street New Orleans, Louisiana	Obviousness of claimed invention
Winkel, Craig 2508 Whitings Neck Road Martinsburg, WV 25401-0513	Nexus between claimed invention and any alleged commercial success; effectiveness of claimed invention as an oral contraceptive

Barr's May Call List

Witness	Summary
Blode, Harmut Bayer Schering Pharma AG Müllerstraße 178 13342 Berlin, Germany	Pharmacokinetics of drospirenone and other compounds.
Duesterberg, Bernd Zudeneichen 18 06604 Oberkraemer Germany	Studies regarding the dosage of drospirenone, declaration submitted to USPTO
Elliesen, Jorg Veltheimstrasse 119 13467 Berlin Germany	Declaration filed with the USPTO to overcome patentability rejection.
Ellman, Herman Warner Chilcott 100 Enterprise Drive Rockaway, New Jersey 07866	Clinical trials of the claimed invention; declaration filed with the USPTO to overcome patentability rejection.
Frick, Jeffrey Hill & Knowlton 909 Third Avenue New York, New York 10022	Alleged commercial success of claimed invenmtion.
Funke, Adrian Bayer Schering Pharma AG Müllerstraße 178 13442 Berlin, Germany	Development and testing of the claimed Invention; declaration filed with the USPTO to overcome patentability rejection.
Heil, Wolfgang Am Wasserturm 24 21435 Stefle, Germany	Development and testing of the claimed invention.
Heithecker, Renate Bayer Schering Pharma AG Müllerstraße 178 13442 Berlin, Germany	Conception and reduction to practice of claimed invention; European Phase I, II, and III clinical trials related to claimed invention.
Hümpel, Michael Singenor Weg 24 1463 Berlin, Germany	Conception and reduction to practice of claimed invention..
Lipp, Ralph 11780 Auburn Creek Crossing Zionsville, Indiana 46077	Conception and reduction to practice of claimed invention.
Pospisil, Jutta Medical Safety Surveillance Muellerstrasse 178 13342 Berlin Germany	Side effects associated with the claimed invention; motivation to develop a low dose oral dose form containing drospirenone

Witness	Summary
Schellschmidt, Ilka Strategic Business Unit Gynecology & Andrology Corp Clin. Cev. G&A FC/HT Sellerstrasse 31 13342 Berlin Germany	Clinical trials of the claimed invention
Velez, Nancy Bayer HealthCare Pharmaceuticals Inc. 340 Changebridge Road Pine Brook, New Jersey 07045	FDA communications regarding NDA No. 21-098.
Woyke, Christian Global regulatory Affairs Female Contraception and Hormone Therapy Muellerstrasse 178 13342 Berlin Germany	The preparation and filing of NDA No. 21-098.

Barr reserves the right to call witnesses designated or offered by Plaintiffs, and also reserves the right to call witnesses not named to rebut evidence offered by Plaintiffs.

Barr Objects to the following witnesses for the reasons stated:

Witness	Summary
Nixon, Larry	Rule 702, 401, 402, 403 – Mr. Nixon's testimony is the subject of a Barr motion-in-limine. Barr alleges that Mr. Nixon attempts to give expert opinions outside the scope of his expertise. Any objections set forth in Barr's objections to Plaintiffs' deposition designations, to the extent applicable.
Arrowsmith-Lowe, Janet	Rule 702, 401, 402, 403 – Ms. Arrowsmith-Lowe's testimony regarding FDA approval is irrelevant; Ms. Arrowsmith-Lowe's testimony is the subject of a Barr motion-in-limine. Any objections set forth in Barr's objections to Plaintiffs' deposition designations, to the extent applicable.
Velez, Nancy	Rule 401, 402, 403 - The FDA regulatory approval is irrelevant to current proceedings; Barr has filed a motion-in-limine seeking the preclusion of any testimony of FDA regulations Any objections set forth in Barr's objections to Plaintiffs' deposition designations, to the extent applicable.
Foster, Thomas	Rule 702, 401, 402, 403 – Mr. Foster's testimony regarding HPLC detection limits

Witness	Summary
	irrelevant because it is based on unreliable science. Mr. Foster's testimony is the subject of a Barr motion in limine. Any objections set forth in Barr's objections to Plaintiffs' deposition designations, to the extent applicable.
Schulman, Lee	Rule 702, 401, 402, 403 - relevance and subject of motion in limine regarding FDA guidelines

B. On damages, Defendant intends to call the following witnesses who will testify in accordance with the following summaries:

(none).

C. Plaintiffs object to the following witnesses for the reasons stated:

Barr Witness	Objection
Walter Chambliss	Rule 702 -- Bayer Schering objects to the state of mind testimony Dr. Chambliss is expected to offer, based on his expert report. *See* Bayer Schering's Motion *in Limine*.
Nick Tantillo	Rule 401, 402, 403 -- Bayer Schering objects to the relevance of Mr. Tantillo's testimony. Mr. Tantillo is a fact witness who works in Barr's regulatory department. Because Barr has stipulated to infringement, Mr. Tantillo's testimony about Barr's "decision to file ANDA No. 77-527" has no relevance.

8. EXHIBIT LISTS

A. Joint exhibit list: See attached Tab 1.

B. Plaintiffs' exhibit list with Defendant's objections: See attached Tab 2.

Bayer Schering objects to the addition of previously undisclosed documents to Barr's exhibit list after the Court-ordered deadline of October 25, 2007 (*See* Section 8.C., *infra*.) Barr first notified Bayer Schering of its desire to rely upon these documents on November 8, 2007 (the morning this Order was due and one week before the start of

trial). The late disclosure of new prior art violates the disclosure requirements of the Federal Rules of Civil Procedure and 35 U.S.C. § 282(4).

C. Defendant's exhibit list with Plaintiffs' objections: See attached Tab 3.

Defendants also intend to introduce the following exhibits at trial which were inadvertently omitted from Defendants' proposed exhibit list exchanged with Plaintiff on October 25, 2007:

1. DX-457	U.S. Patent No. 5,756,490
2. DX-458	Encyclopedia of Pharmaceutical Technology, "Enteric Coatings" (1992)
3. DX-459	Physicians Desk Reference for Digoxin Tablets
4. DX-460	Physicians Desk Reference for Erythromycin Tablets
5. DX-462	H. Takahashi et al., *Variability in Absorption Lag Time of Pyridoxal Phosphate Under Fasting and Pre- and Post-Meal Conditions,* Biopharmaceutics & Drug Disposition Volume 15, No. 6 (August 1994)

Barr reserves the right to offer in evidence the exhibits listed in Plaintiffs' Trial Exhibit List, or offered or marked by Plaintiffs. Barr also reserves the right to offer in evidence documents not listed above that are used for cross-examination or impeachment purposes, or on rebuttal.

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IT IS SO ORDERED, this 13 day of November, 2007.

Hon. Peter J. Sheridan, U.S.D.J.

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Joint Trial Exhibits

JTX	Date	Bates Range		Author	Description
JX0001	09/07/2004		-	Hillman, J Lipp, R Heithecker, R Tack, J Huempel, M Heil, W	United States Patent No. 6,787,531: Pharmaceutical Composition for Use as a Contraceptive
JX0002	08/31/2000	SBPL03500000	- SBPL03501840		Certified File History for United States Patent No. 6,787,531; Application No. 09/654,227
JX0003	00/00/1986	SBPL03500637	- SBPL03500647	Nickisch, K Bittler, D Laurent, H Wiechert, R	Article: Acid-Catalyzed Rearrangements of 15B, 16B-Methylene-17a-Pregnene-21,17-Carbolactone Derivatives
JX0004	00/00/1982	SBPL03501290	- SBPL03501298	Krause, W Jakobs, U	Article: Determination of Plasma Levels of Spirorenone, A New Aldosterone Antagonist, and one of its Metabolites by High-Performance Liquid Chromatography, Journal of Chromatography, 1982
JX0005	00/00/1983		-	Krause, W Sack, Ch Seifert, W	Article: Pharmacokinetics of the New Aldosterone Antagonist, Spirorenone, in Healthy Volunteers after Single and Repeated Daily Doses
JX0006	07/00/1982	SBPL03501283	- SBPL3501288	Krause, W Kuhne, G	Article: Isolation and Identification of Spirorenone Metabolites from the Monkey (MACACA Fascicularis)
JX0007	02/27/1990		-	Schulze, P Nickisch, K Laurent, H Pollow, K	United States Patent 4,904,462: Multiply-Tritiated Steroidal-20, 17-Spirolactones and their use as Tracer Compounds.

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Joint Trial Exhibits

JTX	Date	Bates Range		Author	Description
JX0008	00/00/1995	SBPL03500600	- SBPL03500605	Oelkers, W Foidart, J Dombrovicz, N Welter, A Heithecker, R	Article: Effects of a new Oral Contraceptive Containing an Antimineralocorticoid Progestogen, Drospirenone, on the Renin-Aldosterone System, Body Weight, Blood Pressure, Glucose Tolerance, and Lipid Metabolism
JX0009	00/00/1991	SBPL00074890	- SBPL00074895	Oelkers, W Berger, V Bolik, A Bahr, V Hazard, B Beier, S Elger, W Heithecker, R	Article: Dihydrospirorenone, a New Progestogen with Antimineralocorticoid Activity: Effects on Ovulation, Electrolyte Excretion, and the renin-Aldosterone System in Normal Women
JX0010	11/28/2003	SBPL03500740	- SBPL03500982	Ellman, H	Declaration of Herman Ellman, M.D., with Exhibits A-M
JX0011	03/07/2003	SBPL03500618	- SBPL03500680	Lipp, R	Declaration of Ralph Lipp
JX0012	03/00/1999	SBPL00407483	- SBPL00407506		Trial Master File - 92052 - DE00470 - Drospirenone Oral Contraception - Section 17.1 - Final Research Report
JX0013	00/00/1990		-	Duclos, R Clabaut, M Daoust, M Orecchioni, A	Article: Plasma Imidazol Levels in Healthy Volunteers Following Oral Administration of the Salicylic Prodrug in Two Pharmaceutical Formulations
JX0014	00/00/1993		-	Carlson, R Isley, W Ogrinc, F Klobucar, T	Article: Efficacy and Safety of Reformulated, Micronized Glyburide Tablets in Patients with Non-Insulin-Dependent Diabetes Mellitus: A Multicenter, Double-blind, Randomized Trial.

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Joint Trial Exhibits

JTX	Date	Bates Range		Author	Description
JX0015	00/00/1978		-	Fell, J Calvert, R Riley-Bentham, P	Article: Bioavailability of griseofulvin from a novel capsule formulation.
JX0016	07/00/1986		-	Fromming, K Grote, U	Article: Lyophilized preparations of griseofulvin 2nd communication: in vivo release.
JX0017	00/00/1995		-	Muhn, P Fuhrmann, U Fritzmeier, K Krattenmacher, R Schillinger, E	Article: Drospirenone: a Novel Progestogen with Antimineralocorticoid and Antiandrogenic Activity
JX0018	00/00/1996		-	Arias, M Gines, J Moyano, J Rabasco, A	Article: Dissolution properties and in vivo behavior of triamterene in solid dispersions with polyethylene glycols.
JX0019	00/00/1982		-	McInnes, G Asbury, M Ramsay, L Shelton, J	Article: Effect of Micronization on the Bioavailability and Pharmacologic Activity of Spironolactone
JX0020	00/00/1996		-	Fotherby, K	Article: Bioavailability of Orally Administered Sex Steroids Used in Oral Contraception and Hormone Replacement Therapy
JX0021	00/00/0000	SBPL00204587	- SBPL00204587		Personal Data for Renate Heithecker.
JX0022	00/00/1993		-	Hartmann, D Guzelhan, C Crijns, H Peeters, P Persson, P Jonkman, H	Article: Comparison of Galenic Formulations of Orlistat (Tetrahydrolipstatin): A Pharmacological Approach.

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Joint Trial Exhibits

JTX	Date	Bates Range		Author	Description
JX0023	00/00/1989	M-P00000983	- M-P00000987	Shah, J Chen, J Chow, D	Article: Preformation Study of Etoposide: Identification of Physicochemical Characteristics Responsible for the Low and Erratic Oral Bioavailability of Etoposide.
JX0024	12/19/2003	SBPL02680812	- SBPL02680865	Castaneda, S	Protocol for Phase I clinical study - Final version 1.0 No. 308064 - Open-label, non-randomized study to determine the multiple dose pharmacokinetics of Yasmin (3 mg drospirenone + 30 ug ethinyl estradiol) after oral administration in a 21-day regimen in healthy young Chinese women.
JX0025	08/29/1996	SBPL02444729	- SBPL02444732	Eder, W	Minutes of the DRSP-OC Meeting August 28, 1996 at Berlex, Wayne
JX0026	01/00/2002		-	Berlin, J Tutsch, K Arzoomanian, R Alberti, D Binger, K Feierabend, C Dresen, A Marnocha, R Pluda, J Wilding, G	Article: Phase I and Pharmacokinetic Study of a Micronized Formulation of Carboxyamidotriazole, a Calcium Signal Transduction Inhibitor: Toxicity, Bioavailability and the effect of Food.
JX0027	03/23/1995	SBPL02310986	- SBPL02311025		6th Project Team Meeting, February 23, 1995
JX0028	00/00/1972	SBPL03501144	- SBPL03501145	Kincl, F Ciaccio, L Benagiano, G	Article: Short Communication: Increasing Oral Bioavailability of Progesterone by Foundation
JX0029	05/29/1997	SBPL02453554	- SBPL02453558	Nashed, N Doring, E	OC with Drospirenone (Yasmin®) 14th Project Team Meeting DE-00470, May 29, 1997.

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Joint Trial Exhibits

JTX	Date	Bates Range		Author	Description
JX0030	00/00/1977		-	Kohno, K Takeuchi, Y Etoh, A Noda, K	Article: Pharmacokinetics and Bioavailability of Diltiazem (CRD-401) in Dog.
JX0031	00/00/1983	M-P00000968	- M-P00000979	Montel, J Mulak, G Cotty, J Chanoine, F Rovei, V	Article: Development of a New Tablet Formulation of Theophylline: in Vitro and in Vivo Studies
JX0032	00/00/2002	SBPL02588858	- SBPL02588858		Yasmin Marketing Strategies 2002.
JX0033	00/00/0000	SBPL00000341	- SBPL00000569		NDA Drospirenone 3 mg and Ethinyl Estradiol 0.030 mg Tablets
JX0034	05/14/1999	SBPL00263112	- SBPL00263114	Velez, N	NDA 21-098 - Yasmin 21/28 Tablets (Drospirenone 3 mg and Ethinyl Estradiol 0.030 Tablets) Original New Drug Application.

Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0007	09/14/1983	SBPL02452131	-SBPL02452132	Tack, J	Memo re: Instability of ZK 30595 in Hydrochloric Acid Medium	Subject to motion in limine re: internal documents as evidence of non-obviousness; hearsay (Rule 802); relevance (Rule 402, 403); authentication (Rule 901)
PTX0008	03/11/1981	SBPL00002490	-SBPL00002496	Krause, W	Report No. 4627: Acid-catalyzed rearrangement of ZK 30 595 and ZK 35 973.	Subject to motion in limine re: internal documents as evidence of non-obviousness; hearsay (Rule 802); relevance (Rule 402, 403)
PTX0009	00/00/1996	SBPL00074836	-SBPL00074844	Fuhrmann, U Krattenmacher, R Fritzmeier, K Slater, E	Article: The Novel Progestin Drospirenone and its Natural Counterpart Progesterone: Biochemical Profile and Antiandrogenic Potential	Hearsay (Rule 802)
PTX0010	02/05/1988	SBPL03501537	-SBPL03501579	Tack, J	Tack Invitation to the Doctoral Candidates' Colloquium on 2/17/88 re "Studies on pH-Dependent Isomerization of Prednenc-17,21-Carbolactones-Are Gastric-Juice-Resistant Dosage Forms Necessary?" and slide presentation thereon.	Hearsay (Rule 802); best evidence (Rule 901)
PTX0011	00/00/1998		-	Aulton, M York, P	Chapter 1: The Design of Dosage Forms, Pharmaceutics: The Science of Dosage Form Design	Hearsay (Rule 802)
PTX0012	07/13/1988	SBPL00011265	-SBPL00011297	Huempel, M	Report No. 8235: Absolute and relative bioavailability of ZK 30 595 after oral administration of SH T 470 C and SH T 470 D, respectively to 8 young women	Subject to motion in limine re: internal documents as evidence of non-obviousness; hearsay (Rule 802); relevance (Rule 402, 403); authentication (Rule 901)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0014	00/00/1984		-	Casals-Stenzel, J Buse, M Wambach, G Losert, W	Article: The Renal Action of Spirorenone and other 6B, 7B, 15B, 16B-Dimethlene-17-Spirolactones, a new type of Steroidal Aldosterone Antagonists	Hearsay (Rule 802); relevance (Rule 402, 403)
PTX0017	07/17/1985	SBPL02287828	-SBPL02287859	Kuhnz, W	Report No. 6737: Pharmacokinetics of ZK 30 595 following a single oral dose of 1 mg, 5 mg and 10 mg as a tablet resistant to gastric fluid (SH T 470 B) to 5 young women	Hearsay (Rule 802), authentication (Rule 901)
PTX0018	05/19/2004	SBPL03501702	-SBPL03501716	Funke, A	Declaration of Adrian Funke	Hearsay (Rule 802)
PTX0019	00/00/1988		-	Aulton, M Proudfoot, S	Chapter 9: Factors influencing bioavailability: factors influencing drug absorption from the gastrointestinal tract, Pharmaceutics: The Science of Dosage Form Design	Hearsay (Rule 802)
PTX0022	04/03/1997	SBPL03500481	-SBPL03500529	Elliesen, J	WO97/11680: Hormone Replacement Therapy Method and Hormone Dispenser.	Hearsay (Rule 802)
PTX0023	07/17/1985	SBPL00087861	-SBPL00087871		Report No. 6632: Radioimmunological determination of ZK 30 595 in specimens of human plasma .	Hearsay (Rule 802); authentication (Rule 901)
PTX0024	10/00/1998	SBPL02663164	-SBPL02663182	Blode, H Kuhnz	Pharmacokinetics of Drospirenone (ZK 30595) in humans	Hearsay (Rule 802); best evidence (Rule 1002);
PTX0025	04/20/1998	SBPL00031511	-SBPL00031922	Heithecker, R	Report No. AI51: A multicenter, open-labeled, randomized study on cycle control and tolerance of SH T 470 FA in comparison with Marvelon in up to 26 cycles under long-term contraceptive use.	Hearsay (Rule 802); authentication (Rule 901)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0026	01/10/1995	SBPL02086580	-SBPL02086630	Sander	Working Report No. KQ91E020: Studies on the Isomerization of drospirenone (ZK 30595) into ZK 35096 during dissolution of SH T 470 FA film-coated tablets	Subject to motion in limine re: internal documents as evidence of non-onbviousness; hearsay (Rule 802); relevance (Rule 402, 403); authentication (Rule 901)
PTX0027, PTX0179	10/07/1996	SBPL00077353	-SBPL00077355	Brown, S	IND cover letter, Drospirenone and Ethinyl Estradiol Tablets	Hearsay (Rule 802); best evidence (Rule 1002); authentication (Rule 901)
PTX0028	10/11/1989	SBPL00091298	-SBPL00091382		Report No. 8644: The influence of ZK 30 595 on the renin-angiotensin-aldosterone system (supplement to study 87 004).	Hearsay (Rule 802); relevance (Rule 402, 403); authentication (Rule 901)
PTX0029	09/21/2007		-	Nixon, L	Larry Nixon Curriculum Vitae	Hearsay (Rule 802)
PTX0030	05/00/2005		-	Grimes, D Schulz, K	Article: Surrogate End Points in Clinical Research: Hazardous to Your Health	Hearsay (Rule 802)
PTX0031	00/00/1996	SBPL00010567	-SBPL00010569	Krattenmacher, R Debrindt, C Hegcle-Hartung, C	Article: Effects of drospirenone on blood pressure and heart rate in rats measured by highly sensitive radiotelemetry	Hearsay (Rule 802); relevance (Rule 402, 403)
PTX0032	00/00/1995		-	Rosenberg, M Waugh, M Meehan, T	Article: Use and Misuse of Oral Contraceptives: Risk Indicators for Poor Pill Taking and Discontinuation	Hearsay (Rule 802)
PTX0033	00/00/1998		-	Rosenberg, M Waugh, M	Article: Oral contraceptive discontinuation: A prospective evaluation of frequency and reasons	Hearsay (Rule 802)
PTX0034	04/00/1998		-	Rosenberg, M Waugh, M Burnhill, M	Article: Compliance, Counseling and Satisfaction with Oral Contraceptives: A Prospective Evaluation	Hearsay (Rule 802)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0035	00/00/1995		-	Rosenberg, M	Article: Unintended pregnancies and use, misuse and discontinuation of oral contraceptives	Hearsay (Rule 802)
PTX0036	03/26/1997	SBPL00710845	-SBPL00710854	Brown, S	Letter re: IND 51,693 - Serial No. .008 Drospirenone / Ethinyl Estradiol (DRSP/ EE) Tablets Other: Letter of Understanding.	Subject to motion in limine re: internal documents as evidence of non-obviousness; hearsay (Rule 802); authentication (Rule 901); best evidence (Rule 1002)
PTX0037	00/00/2002	SBPL02598167	-SBPL02598171	Blode, H	Article re: Pharmacokinetics of drospirenone.	Hearsay (Rule 802)
PTX0040	00/00/0000		-	Shulman, L	Lee Shulman Curriculum Vitae	Hearsay (Rule 802)
PTX0041	02/05/1998		-	Gast, M	WO 98/04269 ('the '269 PCT publication), Monophastic Contraceptive Method and Kit Comprising a Combination of a Progestin and Estrogen.	Hearsay (Rule 802)
PTX0042	04/03/1997		-	Elliesen, J Riedl, J	WO 97/11680 re: Hormone Replacement Therapy Method and Hormone Dispenser.	Hearsay (Rule 802)
PTX0043	11/15/1996	SBPL00549349	-SBPL00549352		Data correction sheet for subject 786	Incomplete (Rule 106); hearsay (Rule 802); foundation; authentication (Rule 901); relevance (Rule 402, 403)
PTX0044	05/10/1994	SBPL00496435	-SBPL00496435	Loock, W	Report AI51: Documentation of pregnancy -- Subject 755	Incomplete (Rule 106); hearsay (Rule 802); foundation; authentication (Rule 901); relevance (Rule 402, 403)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0045	01/06/1995	SBPL00496462	-SBPL00496462		Report AI51: Documentation of pregnancy -- Subject 786	Incomplete (Rule 106); hearsay (Rule 802); foundation; authentication (Rule 901); relevance (Rule 402, 403)
PTX0046	03/01/1995	SBPL00451544	-SBPL00451544		Report AI51: Documentation of pregnancy -- Subject 398	Incomplete (Rule 106); hearsay (Rule 802); foundation; authentication (Rule 901); relevance (Rule 402, 403)
PTX0047	08/14/1995	SBPL00496178	-SBPL00496178		Report AI51: Documentation of pregnancy -- Subject 289	Incomplete (Rule 106); hearsay (Rule 802); foundation; authentication (Rule 901); relevance (Rule 402, 403)
PTX0048	11/25/1993	SBPL00496481	-SBPL00496482		Report AI51: Documentation of pregnancy -- Subject 836	Incomplete (Rule 106); hearsay (Rule 802); foundation; authentication (Rule 901); relevance (Rule 402, 403)
PTX0049	06/00/2005		-	Glaxo	Lanoxicaps (digoxin solution in capsules) Prescribing Information	Relevance (Rule 402, 403)
PTX0050	01/16/1997	SBPL02713487	-SBPL02713488		Data correction sheet for subject 836	Incomplete (Rule 106); hearsay (Rule 802); foundation; authentication (Rule 901); relevance (Rule 402, 403)
PTX0051	03/24/1997	SBPL00549354	-SBPL00549354		Data correction sheet for subject 289	Incomplete (Rule 106); hearsay (Rule 802); foundation; authentication (Rule 901); relevance (Rule 402, 403)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0052	06/16/1997	SBPL00549355	-SBPL00549355		Data correction sheet for subject 295	Incomplete (Rule 106); hearsay (Rule 802); foundation; authentication (Rule 901); relevance (Rule 402, 403)
PTX0053	09/17/1997	SBPL00406573	-SBPL00406574	Kulner, A	Authorization for AI51 data release	Relevance (Rule 402, 403); hearsay (Rule 802)
PTX0054	10/17/1997	SBPL00032594	-SBPL00032601	Gerlinger, C	Biometric evaluation of AI51	Relevance (Rule 402, 403); hearsay (Rule 802)
PTX0055	01/16/1998	SBPL00032602	-SBPL00032604	Gerlinger, C	Addendum 1 to biometric evaluation of AI51	Relevance (Rule 402, 403); hearsay (Rule 802)
PTX0056	03/25/1998	SBPL00032605	-SBPL00032609	Gerlinger, C	Addendum 3 to biometric evaluation of AI51	Relevance (Rule 402, 403); hearsay (Rule 802)
PTX0057	08/14/1995	SBPL00496330	-SBPL00496330		Report AI51: Documentation of pregnancy -- Subject 295	Incomplete (Rule 106); hearsay (Rule 802); foundation; authentication (Rule 901); relevance (Rule 402, 403)
PTX0058	04/06/1992	SBPL00091383	-SBPL00091478		Report No. 9692: Clinical data parameters of the Renin-Anglotensin-Aldosterone-System (RAAS) and electrolytes following oral administration of ZK 30.595 in combination with ethinylestradiol (EE).	Hearsay (Rule 802); authentication (Rule 901)
PTX0059	05/15/1992	SBPL00090217	-SBPL00090499	Heithecker, R	Report No. 9693: Investigation of hormonal and metabolic parameters following oral administration of ZK 30.595 in combination with ethinylestradiol (EE)	Hearsay (Rule 802); authentication (Rule 901)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0060	09/02/1992	SBPL00041369	-SBPL00041643	Heithecker, R	Report No. 9970: Study of the influence of SH T 470 F SH T 470 I and SH T 470 K on parameters of the renin-anglotensin-aldosterone system (RAAS), electrolyte metabolism and lipid and carbohydrate metabolism.	Hearsay (Rule 802); authentication (Rule 901)
PTX0061	02/25/1993	SBPL00012889	-SBPL00013027		Report No. 9776: Investigation on the pharmacokinetic interaction of ZK 30 595 and ethinylestradiol following a single oral dose of 3 mg ZK 30 595 as well as the combination 3 mg ZK 30 595+30 ug ethinylestradiol.	Hearsay (Rule 802); authentication (Rule 901)
PTX0062	05/28/1993	SBPL00089793	-SBPL00090215		Report No. A470: Pharmacokinetics of drospirenone and ethinylestradiol following oral administration of SH T 470 E and SH T 470 F to female volunteers.	Hearsay (Rule 802); authentication (Rule 901)
PTX0063	07/01/1993	SBPL00088054	-SBPL00088488		Report No. 9274: Controlled study on pharmacodynamics and pharmacokinetics of the combination drospirenone / ethinylestradiol over 3 months with Microgynon as a reference.	Hearsay (Rule 802); authentication (Rule 901)
PTX0064	03/08/1994	SBPL00104049	-SBPL00104445	Heithecker, R Blode, H	Report No. A187: Study of the Cycle Control, Contraceptive Reliability and Tolerance of SH T 470 F, SH T 470 I and SH T 470 K in Comparison to Microgynon®.	Hearsay (Rule 802); authentication (Rule 901)
PTX0065	05/19/1995	SBPL00092791	-SBPL00092858	Blode, H	Report No. A733: Influence of food intake on the resorption and the systemic availability of drospirenone (DRSP) and ethinylestradiol (EE) after single oral administration of 6 mg DRSP in combination with 60 ug EE.	Hearsay (Rule 802); authentication (Rule 901)
PTX0066	09/05/1995	SBPL00022667	-SBPL00022940	Heithecker, R	Report No. AE91: Open-labeled, randomized study of the influence of the oral contraceptives SH T 470 FA and SH T 470 IA on hemostasis in comparison with Marvelon.	Hearsay (Rule 802); authentication (Rule 901)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0067	04/10/1996	SBPL00038470	-SBPL00038735	Heithecker, R	Report No. AG44: Unicenter, open-labeled, randomized study on the influence of SH T 470 FA on parameters of the hemostatic system and on parameters of the renin-angiotensin-aldosterone system (RAAS) in comparison with Marvelon in 60 healthy women over 13 cycles.	Hearsay (Rule 802); authentication (Rule 901)
PTX0068	08/26/1996	SBPL00028062	-SBPL00028315	Heithecker, R	Report No. AH37. A single-blind, randomized, comparative study with the oral contraceptives SH T 470 F and SH T 470 I in comparison with Marvelon in women with acne and seborrhea over 9 treatment cycles.	Hearsay (Rule 802); authentication (Rule 901)
PTX0069	12/19/1996	SBPL00014281	-SBPL00014401	Blode, H	Report No. AI98: A One-Year Pharmacokinetic Study with the Oral Contraceptive.	Hearsay (Rule 802); authentication (Rule 901)
PTX0070	05/08/1998	SBPL00029763	-SBPL00029956	Loock, W	Report No. AM91: Double-blind, randomized, multicenter, parallel group comparison of SH T 470 FA and Microgynon over 3 cycles in women with premenstrual syndrome (PMS).	Hearsay (Rule 802); authentication (Rule 901)
PTX0071	04/22/1998	SBPL00019936	-SBPL00020307	Schellschmidt, I	Report No. AJ06: Study of cycle control and tolerance of SH T 470 FA in comparison with Marvelon in up to 2100 healthy women over 13 cycles of contraceptive use.	Hearsay (Rule 802); authentication (Rule 901)
PTX0072	05/26/1998	SBPL00039356	-SBPL00039747	Heithecker, R	Report No. AL84: Single-center, open, randomized study on the influence of SH T 470 FA on lipid and carbohydrate metabolism in comparison to Marvelon in 60 healthy women under 13 cycles of contraceptive use.	Hearsay (Rule 802); authentication (Rule 901)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0073	06/17/1998	SBPL00027260	-SBPL00027430	Schellschmidt, I	Report No. AM90: Open, randomized, multicenter study on endometrial morphology in healthy women requiring or agreeing to contraceptive protection under SH T 470 FA over 13 treatment cycles in comparison to the pretreatment value.	Hearsay (Rule 802); authentication (Rule 901)
PTX0074	06/18/1998	SBPL00029034	-SBPL00029306	Loock, W	Report No. AM80: Double-blind, randomized, multicenter study with SH T 470 FA in comparison with Diane 35 in women with acne over 9 treatment cycles.	Hearsay (Rule 802); authentication (Rule 901)
PTX0075	08/19/0000	SBPL01017717	-SBPL01017867		Yasmin® sales figures, 2001-2006	Subject to Plaintiffs' letter dated 10/30/07 re: financial documents, Plaintiffs admitted to Court that this exhibit will be removed from list
PTX0076	00/00/1987		-	Stricker, H	Article: Pharmazeutisch angewandte physikalisch-chemische Grundlagen.	Incomplete (Rule 106); foundation; relevance (Rule 402, 403); hearsay (Rule 802)
PTX0077	08/29/1985	SBPL00090628	-SBPL00090633	Lachnit, U	Report No. 6961: Determination of the transformation dose of the ZK 30 595 (dihydrospirorenone)	Hearsay (Rule 802); authentication (Rule 901)
PTX0078	07/25/1986	SBPL00090643	-SBPL00090657	Holland, U	Report No. 7215: Study of ZK 30 595 (dihydrospirorenone) in respect of inhibition of ovulation.	Hearsay (Rule 802); authentication (Rule 901)
PTX0079	08/25/1988	SBPL02285608	-SBPL02285620		Report No. 8256: Plasma levels of ZK 30 595 and Cyproterone acetote in 2 groups of 6 female volunteers during treatment with daily 2 mg ZK 30 595 or 1 mg Cyproterone acetate over one cycle	Relevance (Rule 402, 403); hearsay (Rule 802); authentication (Rule 901)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0080	09/17/1997	SBPL02799041	-SBPL02799157	Fulcher, A	Research Report No. A951: Investigation of the bioequivalence of drospirenone and ethinyl estradiol from two different tablets each containing 3 mg drospirenone and 0.03 mg ethinyl estradiol and its relative bioavailability with reference to an oral suspension in 42 young women.	Incomplete (Rule 106); authentication (Rule 901)
PTX0084	03/07/2003	M-P00002177	-M-P00002195	Lipp, R	Lipp's Declaration in re application of Wolfgang Heil et al.	Incomplete (Rule 106); hearsay (Rule 802); authentication (Rule 901)
PTX0085	05/14/1988	SBPL00090658	-SBPL00090757	Heithecker, R	Report No. 8036: Human pharmacological comparative study (parameters of renin-angiotensin-aldosterone system and anti-ovulatory effect: Dihydrospirorenone SH T 470 B versus SH 8.0714 Investigator: Professor Dr. W. Oelkers, Steglitz Clinic, Free University of Berlin.	Hearsay (Rule 802); authentication (Rule 901); relevance (Rule 402, 403)
PTX0088	00/00/1979		-	Jones, R Singer, A Edgren, R	Article: The Biological Activities of Norgestrel and its Enantiomers	Relevance (Rule 402, 403); hearsay (Rule 802); foundation
PTX0089	11/29/1983	SBPL02286514	-SBPL02286521		Report 5727 - Analytical proof (HPLC) of ZK 30.595	Subject to motion in limine re: internal documents as evidence of non-obviousness, hearsay (Rule 802); authentication (Rule 901)
PTX0090	07/07/1998	SBPL00010906	-SBPL00011034	Kulmann, H KuhnztBlode, H	Report No. A166	Hearsay (Rule 802); authentication (Rule 901)
PTX0091	02/28/2006		-		Defendant Barr's Supplemental Responses to Plaintiffs' First Set of Interrogatories	

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0092	04/16/2007		-		Defendant Barr Laboratories, Inc.'s Responses to Plaintiffs' Second Set of Interrogatories (Nos. 7-9)	
PTX0093	07/00/1982		-	Krause, W Kuhne, G	Article: Isolation and Identification of Spirorenone Metabolites from the Monkey (Macaca Fascicularis)	Hearsay (Rule 802)
PTX0094	00/00/0000	SBPL01001196	-SBPL01001202		Financial data re Yasmin®.	Hearsay (Rule 802); authenticity (Rule 901)
PTX0095	07/13/1999		-	Elliesen, J Riedl, J	U.S. Patent 5,922,349, Hormone Replacement Therapy Method and Hormone Dispenser.	Relevance (Rule 402,403)
PTX0096	09/00/2007		-		Janet Arrowsmith-Lowe Curriculum Vitae	Hearsay (Rule 802)
PTX0097	00/00/1991		-	Nickisch, K Beier, S Bittler, D Elger, W Laurent, H Losert, W Nishino, Y Schillinger, E Wiechert, R	Article: Aldosterone Antagonists. 4. Synthesis and Activities of Steroidal 6,6-Ethylene-15,16-methylene 17-Spirolactones.	Hearsay (Rule 802); relevance (Rule 402, 403)
PTX0098	00/00/2003		-	Gerlinger, C Endrikat, J Van der Meulen, E Dieben, T Dusterberg, B	Article: Recommendation for confidence interval and sample size calculation for the Pearl Index	Relevance (Rule 402, 403); hearsay (Rule 802); foundation; authentication (Rule 901)
PTX0100	00/00/1985		-	Losert, W Casals-Stenzel, J Buse, M	Article: Progestogens with Antimineralocorticoid Activity	Relevance (Rule 402, 403); hearsay (Rule 802); foundation; authentication (Rule 901)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0103	12/22/1992	SBPL02404120	-SBPL02404142	Hegele-Hartung, Ch.	Report No. A370: Receptor profile and pharmacological actions of ZK 35096	Hearsay (Rule 802); authentication (Rule 901)
PTX0104	11/29/1983	SBPL02293909	-SBPL02293916	Tack, J	Report No. 5728: Acid-catalyzed transformation of ZK 30595 during (in vitro) dissolution test.	Subject to motion in limine re: internal documents as evidence of non-obviousness; hearsay (Rule 802); authentication (Rule 901)
PTX0105	04/14/2006		-		Defendant Barr's Second Supplemental Responses to Plaintiff's First Set of Interrogatories	
PTX0106	11/19/1984	SBPL00087569	-SBPL00087587	Dusterberg, B	Report No. 6335: Pharmacokinetics of ZK 30 595 in the beagle dog. Plasma levels of the total radioactivity and active substance and elimination of the total radioactivity after intravenous and intragastric administration of 3H-ZK 30 595 (0.3 mg/kg).	Hearsay (Rule 802); relevance (Rule 402, 403); authentication (Rule 901)
PTX0107	01/07/1993	SBPL02401763;	-SBPL02401797; SB	Weinig, P Schneider, P Hillman, J	Report APC 67/92 - Working Report KE 84 - Studies on the isomerization of Drospirenone (ZK 30595, Dihydrospirorenone) into ZK 35096, Study no. 92/127	Subject to motion in limine re: internal documents as evidence of non-obviousness; hearsay (Rule 802); authentication (Rule 901)
PTX0108	09/28/1987	SBPL00010166	-SBPL00010185		Report No. 7797: Plasma level of the unchanged drug after a single oral administration of 1 mg ZK 30 595 as a normal tablet (SH T 470 A) and as a film-coated tablet resistant to gastric juice (SH T 470 S) to 6 female beagle dogs.	Hearsay (Rule 802); authentication (Rule 901)
PTX0109	07/09/1996		-	De Castro, L	U.S. Patent 5,534,270, Method of Preparing Stable Drug Nanoparticles.	

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0110	00/00/1991		-	Oelkers, W	Article: Effects of oral contraceptives on the renin-aldosterone system: overview and report on a new natriuretic progestogen	Hearsay (Rule 802)
PTX0111	11/03/2000	SBPL00208530	-SBPL00208727	Kelly, A	Safety Report: Protocol 97036D - Amendment 1: A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy of a Monophastic Oral Contraceptive Preparation, Containing Drospirenone 3 mg and Ethinyl Estradiol 30 ug, in the Treatment of Premenstrual Syndrome (PMS) and premenstrual Dysphoric Disorder (PMDD)	Relevance (Rule 402, 403); hearsay (Rule 802); foundation; authentication (Rule 901)
PTX0112	02/17/2003	SBPL02840794	-SBPL02840794		Email chain re: Yasmin	Relevance (Rule 402, 403); hearsay (Rule 802); foundation; authentication (Rule 901)
PTX0113	01/28/1999	SBPL00270396	-SBPL00270440	Velez, N	PowerPoint slides re: Yasmin® Pre-NDA Meeting.	Relevance (Rule 402, 403); hearsay (Rule 802); foundation; authentication (Rule 901)
PTX0114	02/11/1999	SBPL02302487	-SBPL02302520	Heil, W Lipp, R Voss Schubert	Report No. N580E010: SH T 470 FA Film-Coated Tablets, Validation of the manufacturing process.	Relevance (Rule 402, 403); hearsay (Rule 802); foundation; authentication (Rule 901)
PTX0115	07/02/1981	SBPL02453077	-SBPL02453084		Report 4761: Plasma level of ZK 35 973 in money (Macaca fascicularis), 3 hours after 1, 8, 22, and/or 46 administrations of one dosage of 290 mg/kg (samples of study Tox. 30 327)	Relevance (Rule 402, 403); hearsay (Rule 802); foundation; authentication (Rule 901)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0116	00/00/0000	SBPL00711066	-SBPL00711066		Pre-NDA Meeting Package Drospirenone 3 mg and Ethinyl Estradiol 0.030 mg Tablets: Program: DRSP (P96049. SAS.BI90177) BKGTAB.SAS.	Incomplete (Rule 106); relevance (Rule 402, 403); hearsay (Rule 802); foundation; authentication (Rule 901)
PTX0117	07/00/2006		-	R.P. Scherer Bristol Meyers	VePesid (etoposide) Capsules Product Information	Relevance (Rule 402, 403); hearsay (Rule 802); foundation; authentication (Rule 901)
PTX0118	08/23/1999	SBPL02615895	-SBPL02615900	Blode, H	Email re: DRSP isomerization in vivo.	Hearsay (Rule 802); authentication (Rule 901)
PTX0120	00/00/1994		-	Stanczyk, F	Article: Structure-Function Relationships, Potency, and Pharmacokinetics of Progestogens, Chapter 7 of "Treatment of the Postmenopausal Woman: Basic and Clinical Aspects."	Hearsay (Rule 802); relevance (Rule 402, 403)
PTX0122	00/00/0000	SBPL00531336;	-SBPL00531336;	Blode, H	Hartmut Blode Curriculum Vitae.	Hearsay (Rule 802)
PTX0124	03/27/2007		-	Broxterman, E	Letter: confidential information to be disclosed to Harry Boghigian.	Hearsay (Rule 802); relevance (Rule 402, 403); best evidence (Rule 1002)
PTX0126	07/19/1996	SBPL02453577	-SBPL02453584		OC with Drospirenone 11th Project Team Meeting FK.01.470, July 2, 1996.	Hearsay (Rule 802); authentication (Rule 901)
PTX0127	06/18/1996	SBPL02444743	-SBPL02444750		OC with Drospirenone 10th Project Team Meeting FK.01.470, May 23, 1996.	Hearsay (Rule 802); authentication (Rule 901)
PTX0128	10/29/1994	SBPL02798249	-SBPL02799020	Heithecker, R Blode, H	Report No. A892: A Multicenter, open-label randomized study of the dose-dependency of the ovulation-inhibitory effect under oral administration of drospirenone for one cycle	Hearsay (Rule 802); authentication (Rule 901)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0129	11/10/2005		-		Defendant Barr's Response to Plaintiffs' First Set of Interrogatories	
PTX0130	05/02/2007		-		Defendant Barr's Responses to Plaintiffs' Third Set of Interrogatories (Nos. 10-12)	
PTX0131	08/17/2007		-		Joint Proposed Order re schedule	
PTX0132	07/01/1993	SBPL02293918	-SBPL02293957	Hilmann	Report No. KE 84 re Studies on the isomerization of Drospirenone (ZK 30595, Dihydrospirorenone) into ZK 35096.	Hearsay (Rule 802); authentication (Rule 901)
PTX0134	01/11/1977		-	Gardella, L	U.S. Patent 4,002,718 re: Gelatin-encapsulated Digoxin Solutions and Method of Preparing the Same.	Relevance (Rule 402, 403)
PTX0135	10/00/1997		-	Shulman, L	Article: Compliance and Contraception Sharing Responsibility for Improving Outcomes.	Hearsay (Rule 802)
PTX0136	02/12/1997	SBPL00076642;	-SBPL00076693;	Brown, S	Contact Report of meeting between Berlex and Division of Reproductive and urologic Drug Products.	Subject to motion in limine re internal documents as evidence of non-obviousness; hearsay (Rule 802)
PTX0137	00/00/1980		-	Notari, R	Chapter on "Absorption of Drugs from Gastrointestinal Tract."	Hearsay (Rule 802)
PTX0138	00/00/1993		-	Martin, A	Chapter 12 Excerpt: Kinetics, Martin's Physical Pharmacy, 1993	Incomplete (Rule 106); relevance (Rule 402, 403); hearsay (Rule 802)+G151
PTX0139	00/00/0000		-	Healy, J Hardy, J Davis, S Wilson, C	Chapter 7: Enteric Coatings and Delayed Release, Drug Delivery to the Gastrointestinal Tract	Relevance (Rule 402, 403); hearsay (Rule 802)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0140	00/00/1986		-	Davis, S Hardy, J Fara, J	Article: Transit of pharmaceutical dosage forms through the small intestine	Hearsay (Rule 802)
PTX0141	03/15/1977		-	Bruzzese, T Racchelli, L Lomi, R Rognoni, S	Article: Action of Gastric and Intestinal Simulated Juice on Mepartricin in solid and Solubilized Form	Relevance (Rule 402, 403); hearsay (Rule 802)
PTX0142	09/10/2007		-		James McGinity Curriculum Vitae	Hearsay (Rule 802)
PTX0143	00/00/1991		-	Dollery, C	Digoxin -Therapeutic Drugs (ed. Sir Colin Dollery)	Relevance (Rule 402, 403); hearsay (Rule 802)
PTX0144	02/00/1984		-	Doherty, J Marcus, F Binnion, P	Article: A Multicenter Evaluation of the Absolute Bioavailability of Digoxin Dosage Forms.	Relevance (Rule 402, 403); hearsay (Rule 802)
PTX0145	08/25/1964		-	Mancera, O Batres, E	U.S. Patent No. 3,146,244 re Selective Bromination of Isolated Double Bonds in Steroidal Compounds.	Relevance (Rule 402, 403)
PTX0146	09/13/1996	SBPL00549353	-SBPL00549353		Study AI51: Case Report Form for Subject 659	Incomplete (Rule 106); hearsay (Rule 802); foundation; authentication (Rule 901); relevance (Rule 402, 403)
PTX0147	01/01/1995		-		USP 23 Monograph Section 724 re: Drug Release.	Incomplete (Rule 106); relevance (Rule 402, 403); hearsay (Rule 802); authentication (Rule 901)
PTX0148	00/00/1979		-		Excerpt re Digoxin, Pharmaceutical Codex (11th Edition)	Hearsay (Rule 802); relevance (Rule 402, 403)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0149	00/00/2003	SBPL01006163	-SBPL01006322		Schering Annual Report 2003	Hearsay (Rule 802); authentication (Rule 901)
PTX0150	00/00/1993		-	Cohen, A Kroon, R Schoemaker, H Breimer, D Van Vliet-Verbeek, A Brandenburg, H	Article: The bioavailability of digoxin from three oral formulations measured by a specific h.p.l.c assay	Relevance (Rule 402, 403); hearsay (Rule 802)
PTX0152	12/00/2005		-		Yasmin® Patient Package Insert	
PTX0153	03/00/2000	SBPL02318211	-SBPL02318343		Summary of Clinical Trials, European Regulatory Submission	Relevance (Rule 402, 403); authentication (Rule 901)
PTX0155	08/15/1987	SBPL02269870	-SBPL02269879	Riedl, J	Batch Record G879076 SH T 470 D	Foundation; authentication (Rule 901); relevance (Rule 402, 403)
PTX0156	09/10/1987	SBPL02269486	-SBPL02269497	Riedl, J	Batch Record G879075 SH T 470 C	Foundation; authentication (Rule 901); relevance (Rule 402, 403)
PTX0157	10/05/1988	SBPL00500618	-SBPL00500618		Batch Record G888091 SH T 470 A	Foundation; authentication (Rule 901); relevance (Rule 402, 403)
PTX0158	09/21/2007		-	Foster, T	Thomas Foster Curriculum Vitae	Hearsay (Rule 802)
PTX0159	09/19/2000		-	Mohr, J Nickisch, K	U.S. Patent No. 6,121,465 re: Process for Production Drospirenone and Intermediate Products of the Process.	Relevance (Rule 402, 403)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0160	08/27/1997	SBPL00014767	-SBPL00014813	Blode, H	Report No. AI99: Multicenter, open, non-comparative study of the breast milk passage of drospirenone after single oral administration of SH T 470 FA in healthy, lactating women	Hearsay (Rule 802); authentication (Rule 901)
PTX0161	09/10/2007		-		Defendant Barr's Amended Answer, Affirmative Defenses and Counterclaims	
PTX0162	02/12/1997	SBPL00000085	-SBPL00000089	Kish, C	Minutes of Phase III meeting re Drospirenone and ethinyl estradiol.	Subject to motion in limine re internal documents as evidence of non-obviousness, hearsay (Rule 802); authentication (Rule 901)
PTX0163	02/10/1999	SBPL00032617	-SBPL00032842	Muenzen, R	Report No. 98180: An Open-Label, Multicenter Study to Evaluate the Efficacy and Safety of a Monophastic Oral Contraceptive Preparation, Containing Drospirenone (DRSP) 3 mg and Ethinyl Estradiol (EE) 30 ug.	Hearsay (Rule 802); authentication (Rule 901)
PTX0164	00/00/0000	SBPL00031418	-SBPL00031424		NDA Drospirenone 3 mg and Ethinyl Estradiol 0.030 mg Tablets	Hearsay (Rule 802); authentication (Rule 901)
PTX0165	10/02/1996	SBPL00077366	-SBPL00077420		IND Drospirenone/Ethinyl Estradiol Tablets, Item 5.0: Confidential Investigator's Brochure	Hearsay (Rule 802); authentication (Rule 901)
PTX0166	09/13/1996	SBPL00077363	-SBPL000077365		IND Drospirenone/Ethinyl Estradiol Tablets, Introductory Statement and General Investigational Plan	Hearsay (Rule 802); authentication (Rule 901)
PTX0167	10/07/1996	SBPL00077359	-SBPL00077362		IND Drospirenone/Ethinyl Estradiol Tablets, Table of Contents	Hearsay (Rule 802); authentication (Rule 901)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0168	04/00/1997		-	Redmond, G Olson, W Lippman, J Kafrissen, M Jones, T Jorizzo, J	Article: Norgestimate and Ethinyl Estradiol in the Treatment of Acne Vulgaris: A Randomized, Placebo-Controlled Trial	Hearsay (Rule 802); relevance (402, 403)
PTX0169	03/00/2000	SBPL02317475	-SBPL02317491		Yasmin® European Regulatory Submission, Table of Contents	Relevance (Rule 402, 403); hearsay (Rule 802); authentication (Rule 901)
PTX0170			-		Yasmin product sample	Authentication (Rule 901)
PTX0171	06/00/2004		-	Tuleu, C Newton, M Rose, J Euler, D Saklatvala, R Clarke, A Booth, S	Article: Comparative Bioavailability Study in Dogs of a Self-Emulsifying Formulation of Progesterone Presented in a Pellet and Liquid Form Compared with an Aqueous Suspension of Progesterone	Relevance (Rule 402, 403); hearsay (Rule 802)
PTX0172	01/28/1992		-	Greco, J McGinity, J	U.S. Patent No. 5,084,277 re: Vaginal Progesterone Tablet.	Relevance (Rule 402, 403)
PTX0173	00/00/1988	SBPL02256119	-SBPL02256131	Riedl, J	Batch Record G888091 SH T 470 A	Foundation; authentication (Rule 901); relevance (Rule 402, 403)
PTX0174	07/13/2000	SBPL00263829	-SBPL00263831	Houn, Florence Dr	Letter re New Drug Application (NDA-21-098)	Hearsay (Rule 802); authentication (Rule 901)
PTX0175	03/17/2000	SBPL00270387	-SBPL00270390	Houn, Florence Dr Best, J	NDA-21098 Yasmin® Approval Letter.	Hearsay (Rule 802); authentication (Rule 901)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0176	03/02/1994	SBPL00479328	-SBPL00479330	Ellman, H	Memo re: FDA standards for Phase III OC development	Hearsay (Rule 802); authentication (Rule 901)
PTX0177	09/12/1996	SBPL00077421	-SBPL00077463	Ellman, H	IND Drospirenone/Ethinyl Estradiol Tablets: 6.0 Protocol.	Hearsay (Rule 802); authentication (Rule 901)
PTX0178	12/04/1998	SBPL00087927	-SBPL00087973		IND Drospirenone/Ethinyl Estradiol Tablets: Overall Summary of Previous Human Experience.	Hearsay (Rule 802); authentication (Rule 901)
PTX0179; PTX0027	10/07/1996	SBPL00077353	-SBPL00077355	Brown, C	Letter submitting initial Investigational New Drug Application (IND).	Hearsay (Rule 802); authentication (Rule 901)
PTX0180	01/00/2007		-		FDA Advisory Committee for Reproductive Health Drugs General Meeting January 23 and 24, 2007	Subject to motion in limine re FDA guidelines; foundation; relevance (Rule 402, 403)
PTX0181	12/00/2001		-	Evelyn, B Tolgo, T Banks, D Pohl, D Gray, E Robins, B Ernat, J	Article: Participation of Racial / Ethnic Groups in Clinical Trials and Race-Related Labeling: A Review of New Molecular Entities Approved 1995-1999.	Relevance (Rule 402, 403); hearsay (Rule 802)
PTX0182	02/20/1997	SBPL02087480	-SBPL02087495	Schneider, P Winter, G Erb, S	Working Report No. LY76: The solubility of Drospirenone, ZK 30 595, in water and aqueous buffer solutions of ph 5, 7 and 9.	Hearsay (Rule 802); authenticity (Rule 901)
PTX0183	00/00/1989		-	Wilson, C Washington, N	Chapter 4: The Stomach: its role in oral drug delivery, Physiological Pharmaceutics Biological Barriers to Drug Absorption	Hearsay (Rule 802)
PTX0184	01/01/1995		-		USP 23 Monograph Section 1151 re: Pharmaceutical Dosage Forms.	Hearsay (Rule 802)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0185	05/26/1992		-	Greco, J McGinity, J	U.S. Patent No. 5,116,619 re: Vaginal Progesterone Tablet.	Relevance (Rule 402, 403)
PTX0186	05/19/2004	M-P00000133	-M-P00000149	Zelano, A	Fax attaching Supplement Amendment for Serial No. 09/654,227	Hearsay (Rule 802); authentication (Rule 901)
PTX0187	05/06/1999	SBPL02305892	-SBPL02305899	Eder, W Bresky, A	Yasmin® 25th Project Team Meeting	Hearsay (Rule 802); authentication (Rule 901)
PTX0188	02/00/1998		-	Peterson, L Oakley, D Potter, L Darroch, J	Article: Women's Efforts to Prevent Pregnancy: Consistency of Oral Contraceptive Use	Hearsay (Rule 802)
PTX0189	10/13/1997	SBPL02314714	-SBPL02314722	Weiss, R	Minutes of PCME Technical Exchange Meeting ON Yasmin 30, DE-00470	Hearsay (Rule 802); authentication (Rule 901)
PTX0190	11/27/1996	SBPL02301750	-SBPL02301758	Weiss, R	Minutes of PCME Technical Exchange Meeting Drospirenone, November 27, 1996.	Hearsay (Rule 802); authentication (Rule 901)
PTX0191	03/31/1998	SBPL02419913	-SBPL02419945	Hilmann Heil, W	Working Report No. MK02E010: SH T 470 FA Film-coated Tablets Development of Formulation and Manufacturing Process.	Hearsay (Rule 802); authentication (Rule 901)
PTX0192	06/22/1993	SBPL02285768	-SBPL02285770		Status report on the absorption, distribution, metabolism and excretion (ADME) of Drospirenone (ZK 30 595) in animal species and man.	Hearsay (Rule 802); authentication (Rule 901)
PTX0193	04/01/1980	M-P00000843	-M-P00000847	Besins, J	U.S. Patent No. 4,196,188 re: Orally Administrable Form of Progesterone.	
PTX0194	07/23/2004	SBPL02606024	-SBPL02606025		Report re prescriptions, NDC Health Prescription Database and samples.	Hearsay (Rule 802); authentication (Rule 901)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0195	07/22/1988	SBPL00500110	-SBPL00500111	Riedl, J	Batch Record G868056 SH T 470 B	Foundation; authentication (Rule 901); relevance (Rule 402, 403)
PTX0196	09/08/1986	SBPL02256277	-SBPL02256288	Riedl, J	Batch Record G868056 SH T 470 B	Foundation; authentication (Rule 901); relevance (Rule 402, 403)
PTX0197	04/06/2004	M-P00002328	-M-P00002329	Hui, Examiner	Interview Summary from 4/6/04 in re Application 09/654,227	Hearsay (Rule 802); authentication (Rule 901)
PTX0198	07/25/1986	SBPL00499853	-SBPL00499857	Lachnit, U	Report No. 7214: Extended study of ZK 30 595 (dihydrospirorenone) in respect of the inhibition of ovulation.	Relevance (Rule 402, 403); hearsay (Rule 802); authentication (Rule 901)
PTX0200	00/00/1992		-	Reuning, R Geraets, D Rocci, M Vlasses, P	Chapter 20: Digoxin, Applied Pharmacokinetics, 1992	Relevance (Rule 402, 403); foundation; hearsay (Rule 802)
PTX0201	12/04/2003	M-P00002386	-M-P00002411		Amendments and/or additions to the Claims in re App of Heil Serial No. 09/654, 227 filed 8/31/00	Hearsay (Rule 802)+G138
PTX0203	06/11/1980	SBPL02902458	-SBPL02902468	Kopp, R Humpel, M Krause, W	Report No. 4320: Detection of ZK 35 973 in Plasma.	Hearsay (Rule 802); authenticity (Rule 901); relevance (Rule 402, 403)
PTX0204	00/00/0000	SBPL02306866	-SBPL02306866		Michael Humpel Curriculum Vitae	Hearsay (Rule 802)
PTX0206	00/00/0000	SBPL02293849	-SBPL02293852	Tack, J	Tack Handwritten Notes	Hearsay (Rule 802); authenticity (Rule 901); relevance (Rule 402, 403)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0207	04/07/2004	M-P00000025	-M-P00000039	Sopp, J	Fax attaching list of claims with proposed amended claims for Application No. 09/654,227	Hearsay (Rule 802); authenticity (Rule 901); best evidence (Rule 1002)
PTX0208	12/07/1992	SBPL02555828	-SBPL02555874		Report No. A376: Pharmacokinetics of the unchanged drug and the 14C-labelled substance after single intragastric (1 of 10 mg/kg) and intravenous (0.5 mg/kg) administration of 14C-drospirenone to female cynomolgus monkeys.	Hearsay (Rule 802); relevance (Rule 402, 403)
PTX0209	05/23/2007		-		Defendant Barr Laboratories Inc. Responses and Objections to Plaintiffs' Fourth Set of Interrogatories	
PTX0210	00/00/0000	SBPL00102254	-SBPL00102267		Yasmin® Business Plan Draft Outline.	Hearsay (Rule 802); authenticity (Rule 901); relevance (Rule 402, 403)
PTX0211	05/09/1983	SBPL02295585	-SBPL02295591	Meyer-Tischler	Minutes of Joint LE/LAP Meeting re Progestins (ZK 35973 and 30595)	Relevance (Rule 402, 403); authenticity (Rule 901); hearsay (Rule 802); best evidence (Rule 1002)
PTX0214	00/00/2002		-	Dieben, T Roumen, F Apter, D	Article: Efficacy, Cycle Control, and User Acceptability of a Novel Combined Contraceptive Vaginal Ring	Hearsay (Rule 802); relevance (Rule 402, 403)
PTX0215	00/00/1996		-	Mosher, W Bachrach, C	Article: Understanding U.S. Fertility: Continuity And Change in the National Survey Of Family Growth, 1988-1995	Hearsay (Rule 802); relevance (Rule 402, 403)
PTX0216	00/00/1990		-	Goldzieher, J Brody, S	Article: Pharmacokinetics of ethinyl estradiol and mestranol	Hearsay (Rule 802); relevance (Rule 402, 403)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0217	00/00/2003		-	de Visser, S Uchida, N van Vliet-Daskalopoulou, E Fukazawa, I van Doorn, M van den Heuvel, M Machielsen, C Uchida, E Cohen, A	Article: Pharmacokinetic differences between Caucasian and Japanese subjects after single and multiple doses of potential combined oral contraceptive (Org 30659 and EE)	Hearsay (Rule 802); relevance (Rule 402, 403)
PTX0218	03/30/2004	M-P00000040	-M-P00000040	Sopp, J	Fax transmitting Declaration of Ralph Lipp	Hearsay (Rule 802); authenticity (Rule 901);
PTX0219	00/00/0000	SBPL00031478	-SBPL00031481		NDA Drospirenone 3 mg and Ethinyl Estradiol 0.030 mg Tablets: Background and overview of clinical investigations.	Hearsay (Rule 802); ; relevance (Rule 402, 403)
PTX0220	03/00/1999		-	Trussell, James Vaughn, Barbara	Article: Contraceptive Failure, Method-Related Discontinuation And Resumption of Use: Results from the 1995 National Survey of Family Growth	Hearsay (Rule 802); relevance (Rule 402, 403)
PTX0222	07/24/2007		-		Joint Stipulation as to Infringement	
PTX0223	11/17/2006	SBPL03501841	-SBPL03502684		European File History, Int'l App. No. PCT/IB00/01213	Subject to motion in limine re: European proceedings; hearsay (Rule 802); authenticity (Rule 901); relevance (Rule 402, 403)
PTX0224	06/00/1991		-	Pramar, Y Gupta, V	Article: Preformulation Studies of Spironolactone: Effect of pH, Two Buffer Species, Ionic Strength, and Temperature on Stability	Hearsay (Rule 802)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0225	02/12/1999	SBPL00033074	-SBPL00033113		Report 98180 - Clinical Study Report Appendix 16.2.5, An Open-Label, Multicenter Study to Evaluate the Efficacy and Safety of a Monophasic Oral Contraceptive Preparation, Containing Drospirenone (DRSP) 3 mg and Ethinyl Estradiol (EE) 30 mcg	Hearsay (Rule 802)
PTX0227	00/00/0000	SBPL00030991	-SBPL00031415		NDA Drospirenone 3 mg and Ethinyl Estradiol 0.030 mg Tablets	Hearsay (Rule 802); ; relevance (Rule 402, 403)
PTX0228	00/00/0000	SBPL00711013	-SBPL00711042		Pre-NDA Meeting Package Drospirenone 3 mg and/ Ethinyl Estradiol 0.030 mg Tablets: Item 8: Clinical Studies.	Hearsay (Rule 802); authenticity (Rule 901); relevance (Rule 402, 403)
PTX0231	07/25/1986	SBPL00499862	-SBPL00499870	Lachnit, U	Report No. 7214: Extended study of ZK 30 595 (dihydrospirorenone) in respect of the inhibition of ovulation	Hearsay (Rule 802); authenticity (Rule 901)
PTX0232	00/00/0000	SBPL02677734	-SBPL02677805		Yasmin's Business Plan.	Hearsay (Rule 802)
PTX0233	02/10/2005	SBPL02593384; SB	-SBPL02593385; SB	Mathews, L	Client Contact Report.	Hearsay (Rule 802)
PTX0234	03/03/2004	SBPL02599496	-SBPL02599497	Vineis, J	Email re Kaiser - Yasmin.	Hearsay (Rule 802)
PTX0235	03/11/1981	SBPL02304516	-SBPL02304523	Krause, W	Report No. 4627 - Acid catalyzed rearrangement of ZK 30595 and ZK 35973	Subject to motion in limine re: internal documents as evidence of non-obviousness; hearsay (Rule 802); authenticity (Rule 901); relevance (Rule 402, 403)
PTX0236	00/00/0000	BARR-DR-035786	-BARR-DR-035918		Abbreviated new Drug Application Drospirenone and Ethinyl Estradiol Tablets, 3.0 mg/0.03 mg: bioavailability / bioequivalence general information.	Subject to motion in limine re documents related to Defendant's ANDA; hearsay (Rule 802)

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Plaintiff's Trial Exhibits with Defendant's Objections

PTX	Date	Bates Range		Author	Description	Def Objections
PTX0238	00/00/0000	BARR-DR-017928	-BARR-DR-017933		Product Development report for Drospirenone and Ethinyl Estradiol Tablets 3 mg/0.03mg.	Subject to motion in limine re documents related to Defendant's ANDA; hearsay (Rule 802)
PTX0239	08/20/1999	SBPL02327141	-SBPL02327145	Velez, N	Yasmin CC NDA: Summary of 8/18 Telecon - item 6.	Subject to motion in limine re internal documents as evidence of non-obviousness; subject to motion in limine re documents purporting to show FDA's opinion; hearsay (Rule 802); authenticity (Rule 901); relevance (Rule 402, 403)
PTX0240	04/17/2003	BARR-DR-050577	-BARR-DR-050578	Cheung, J	Letter re: Bioequivalence requirements for generic equivalent to Yasmin (Drospirenone and Ethinyl Estradiol, 3 mg/0.03 mg) tablets	Subject to motion in limine re internal documents as evidence of non-obviousness; subject to motion in limine re documents purporting to show FDA's opinion; hearsay (Rule 802); relevance (Rule 402, 403);
PTX0241	08/20/1999	SBPL00263049	-SBPL00263075	Velez, N	NDA 21-098: Yasmin 21/28 Tablets Follow up to August 18, 1999 teleconferences: in vivo isomerization.	Subject to motion in limine re internal documents as evidence of non-obviousness; subject to motion in limine re documents purporting to show FDA's opinion; hearsay (Rule 802); authenticity (Rule 901); relevance (Rule 402, 403)
PTX0242	00/00/0000	BARR-DR-056332	-BARR-DR-056339		Reference Drug: Pharmacy Tracking and Accountability Report.	Hearsay (Rule 802); authenticity (Rule 901); relevance (Rule 402, 403)

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